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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,267	12/31/2001	Sidney Pestka	PBLI-P01-010	9576
28120	7590	01/11/2006	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			PRYOR, ALTON NATHANIEL	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/040,267	<b>Applicant(s)</b> PESTKA, SIDNEY	
	<b>Examiner</b> Alton N. Pryor	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 26-28,31-58,67-70,73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 26,28,31-41-56,58,67-70,73 and 74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's arguments filed 10/07/05 have been fully considered but they are not persuasive. See argument below.

Applicant argues:

- a) Controlled release compositions in Tracey rely on a polymeric matrix to affect the release rate of interferon (IFN). Whereas, instant invention does not rely on a polymeric matrix to control the release of IFN.
- b) Applicant's invention is based on the discovery that treatment of molecules, such as proteins, with organic compounds, can modify their solubility and the release rate. The specification states that the release of IFN is affected by the specific organic solvent used as well as time in organic solvent and concentration of IFN in organic solvent.
- c) Claim 74 recites, "consisting essentially of" and thus, would preclude the presence of a polymeric matrix as required by the cited references.

Examiner argues:

- a) Tracey teaches a polymer solution, containing the metal ion stabilized IFN particle dispersion, is processed to form droplets. The droplets contain polymer solution and metal-stabilized IFN particles. The means for freezing droplets to form microparticles include directing the droplets into a liquefied gas. Microparticles then sink to the surface of frozen ethanol. The liquid gas is subsequently evaporated and microparticles sink into the ethanol as the ethanol thaws. See column 7 lines 1-17. While it is true that instant invention does not

require a polymer matrix, it is important to note that instant invention does not exclude a polymer matrix. Instant invention like Tracey's invention requires the presence of a biopolymer (IFN) and lower alcohol such as ethanol. Applicant's sustained released preparation requires a biopolymer such as IFN, lower alcohol such as ethanol, and an aqueous solvent. See claim 45. Note that Tracey's invention requires the same. See column 6 lines 40-57.

- b) Tracey's invention like instant invention is to a sustained release combination of IFN with a lower alcohol such as ethanol. Although Tracey does not explicitly state that the organic compound (ethanol) modifies the solubility of the IFN or its release, it is inherent / obvious that Tracey's combination would have the same release properties as the combination specified in the instant claims. This would be true since both the prior art and instant invention combinations comprise IFN plus ethanol. Applicant provides no reference to concentration of ethanol and time of IFN exposure to ethanol in the claims. Therefore, this is a moot issue.
- c) It is important to note that the mere mention of "consisting essentially of" in claim 74 does not exclude the polymeric matrix. Note that both inventions require the presence of a polymer (IFN), an organic compound (ethanol), and aqueous solvent. Therefore, it is possible for the instant invention to have a polymer matrix.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-28,31-41,43-56,58,67-70,73,74 are rejected under 35 U.S.C. 102(b) as being anticipated by Tracy et al (US 5711968; 1/27/98). Tracy teaches a formulation comprising interferon prepared by exposure of the interferon to ethanol (alcohol solvent) under conditions wherein a precipitate or lyophilate is formed. See abstract, column 1 lines 31-33, column 7 lines 10-17, Examples 1,2. Tracy teaches that interferon is released from the formulation over a period of up to about 3-6 months (at least 24 hours). See column 2 lines 27-40. Tracy teaches that the formulation as a medicament to be administered to humans and animals. See column 8 lines 34-41. Although Tracey does not describe the release rate of the solvent as described in claim 67, it is inherent that the solvent release rate for both Tracey and instant invention would be the same since both inventions require the same limitations, i.e. a biopolymer (IFN), solvent (ethanol) and an aqueous solvent.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tracey as applied to claims 26-28,31-41,43-56,58,67-70,73,74 above. This rejection is being written to address propanol as the elected solvent. See 102(b) rejection above. Tracey teaches all that is recited in claim 57 except for propanol as the elected solvent. It would have been obvious to one having ordinary skill in the art to use propanol. One would have been motivated to do this since Tracey

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employs ethanol, which is a homolog of propanol. One would have been to do this since homologs have the similar chemical and physical properties and thus, similar activity.

***Election Status***

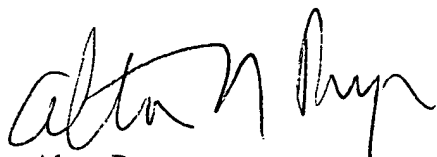
Instant invention comprising IFN and propanol is not allowable. See rejections above.

***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alton Pryor  
Primary Examiner  
AU 1616